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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,276	03/07/2001	John W. Erickson	207596	9981

45733 7590 03/14/2007
LEYDIG, VOIT & MAYER, LTD.
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6731

EXAMINER

LE, EMILY M

ART UNIT	PAPER NUMBER
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1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/720,276

Applicant(s)

ERICKSON ET AL.

Examiner

Emily Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2004 and 26 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47 and 49-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47 and 49-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/9/2005
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/22/2004 has been entered.

Communication

2. The following office action is responsive to the communications filed 11/22/2004. While the records indicate that a non-final office action has been issued to Applicant, however, it is noted that said office action is inadvertently directed to a different set of claims. Hence, in view of this, the office action is vacated.

Also, the Office truly regrets the inconvenience caused by the unintentional delay in the issuance of this office action.

Status of Claims

3. Claims 1-46 and 48 are cancelled. Claims 79-80 are added. Claims 67-78 were previously added. Claims 47 and 49-80 are under examination.

Oath/Declaration

4. In view of the papers filed 02/26/2007, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37

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CFR 1.48(a). The inventorship of this application has been changed by the addition of **Arun Ghosh**.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 47 and 49-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vazquez et al.¹

The claims are directed to a method comprising the active step(s) of administering a compound of the formula recited in the claims to HIV (retrovirus) infected mammal.

Vazquez et al. teaches a compound having the same structure and empirical formula as those recited in the claims, when X is an O, R₅ is a C₄ alkyl, and Ar is an amino substituted phenyl. It is noted that the compound of Vazquez et al. is an isomer of the compound recited in claims 51-59, 69-78 and 80; however, it should be noted that compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) are generally of sufficiently close

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structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977) See also In re May, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers prima facie obvious). Hence, it is presumed that the isomer of Vazquez et al. has similar properties as those recited in the specified claims.

Vazquez et al. does not teach the administration of the compound to an HIV infected mammal.

However, Vazquez et al. teaches that the compounds are effective as retroviral proteases inhibitors, in particular as inhibitors of HIV protease. [Abstract] Vazquez et al. also suggests the administration of the compounds to inhibit retroviral proteases.

[Claims 15-20, page 273.]

Hence, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to administer the composition to an HIV infected mammal. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to inhibit the action of HIV proteases. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because Vazquez et al. teaches that the compound inhibits HIV proteases.

In the instant case, it is noted that claims 60-62 require that the mammal be infected with a wild type HIV, mutant HIV having at least one protease mutation, and a mutant HIV having at least one reverse transcriptase mutation, respective. It is further

¹ Vazquez et al. WO 95/06030, published March 02, 1995.

noted that claims 64-67 and 78 are directed at requiring the mammal to be infected with a multidrug resistant mutant retrovirus, multidrug resistant HIV, a multidrug-resistant HIV-1, and a mutant retrovirus that is resistant to at least one antiviral agent selected from the group consisting of ritonavir, indinavir, amprenavir and saquinavir, respectively. Additionally, it is noted that claim 80 requires the mammal be infected with a multidrug-resistant HIV-1 comprising a protease with at least one mutation selected from the group consisting of V82F, I84V, G48V and V82A.

In summation, claims 60-62, 64-67, 78 and 80 require the mammal to be infected with variations of the HIV virus. To address these limitations, it should be noted that Vazquez et al. teaches a compound having the same formula as those recited in the claims. Vazquez et al. teaches that the compound inhibits retroviral protease, including HIV. In the instant case, Vazquez et al. explains that the correct processing of the precursor proteins by the retroviral protease is necessary for assembly of infectious virions. Vazquez et al. further provides an example. Vazquez et al. states that, as an example, "it has been shown that frameshift mutations in the protease region of the pol gene of HIV prevents processing of the gag precursor protein. It has also been shown through site-directed mutagenesis of an aspartic acid residue in the HIV protease active site that processing of the gag precursor protein is prevented." Hence, on the basis of this showing, Vazquez et al. suggests the administration of the compound having the same formula as recited in the claims to inhibit retroviral replication by inhibiting the action of the retroviral proteases. [Paragraph bridging pages 1-2]

In view of this teaching, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to administer the compound to all HIV infected mammals, regardless of the condition of the virus. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to inhibit the action of HIV proteases. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because Vazquez et al. teaches that the compound inhibits HIV proteases.

Conclusion

7. No claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bruce R. Campell
Supervisory Patent Examiner
Art Unit 1648

Cheryl Le
E. Le
3/08/07



BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

This declaration is of the following type:

- ☐ original ☐ design ☐ supplemental
☒ national stage of PCT
☐ divisional ☐ continuation ☐ continuation-in-part

My residence, post office address, and citizenship are as stated below next to my name. I believe I am the original, first, and sole inventor (*if only one name is listed below*) or an original, first, and joint inventor (*if plural names are listed below*) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

FITNESS ASSAY AND ASSOCIATED METHODS

the specification of which:

- ☐ is attached hereto.
☒ was filed on December 21, 2000 as Application No. 09/720,276 and was amended on (if applicable).
☐ was filed by Express Mail No. as Application No. not known yet, and was amended on (if applicable).
☐ was filed on as PCT International Application No. PCT/ and was amended pursuant to PCT Article 19 on (if any).

I state that I have reviewed and understand the contents of the specification identified above, including the claim(s), as amended by any amendment referred to above.

I acknowledge the duty to disclose information that is material to the patentability of the application identified above in accordance with 37 CFR 1.56.

I claim foreign priority benefits under 35 USC 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate or 365(a) of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent, utility model, design registration, or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter and having a filing date before that of the application(s) from which the benefit of priority is claimed.

PRIOR FOREIGN PATENT, UTILITY MODEL, AND DESIGN REGISTRATION APPLICATIONS					
COUNTRY	PRIOR FOREIGN APPLICATION NO.	DATE OF FILING (day,month,year)	PRIORITY CLAIMED		
			YES		NO
			YES		NO
			YES		NO

Inventorship change approved—
see papers filed 2/26/07
BRUCE R. CAMPELL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600